March 14, 2025

Korot Co. Ltd.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K250091
Trade/Device Name: KOROT Blood Pressure Monitor (KOROT P3 Accurate)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: March 13, 2025
Received: March 13, 2025

Dear Dave Yungvirt:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Robert T. Kazmierski -S

for

LCDR Stephen Browning
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics, and
Monitoring Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250091

Device Name
Blood Pressure Monitor (KOROT P3 Accurate)

Indications for Use *(Describe)*
This blood pressure monitor is designed to measure blood pressure (diastolic and systolic) and pulse rate in adult patients with arm circumference range between 22 cm - 52 cm.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Prepared on: 2025-03-12
510(k)#: K250091

Contact Details	
Applicant Name	KOROT Co., Ltd.
Applicant Address	1-102, 330, Yeongok-gil, Ipjang-myeon, Seobuk-gu, Cheonan-si, Chungcheongnam-do, 31026 Korea, South
Applicant Contact telephone	827040166745
Applicant Contact	Mr. Muyeol Lee
Applicant Contact Email	jimmy@inbody.com
Device Name	
Device Trade Name	KOROT Blood Pressure Monitor (KOROT P3 Accurate)
Common Name	Noninvasive blood pressure measurement system
Classification Name	System, Measurement, Blood-Pressure, Non-Invasive
Regulation Number	870.1130
Product Code(s)	DXN

Legally Marketed Predicate Devices

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221764	Blood Pressure Monitor	DXN

Device Description Summary

The KOROT P3 Accurate is a digital monitor intended for use in measuring blood pressure and pulse rate in adults with upper arm circumference ranging from 22cm to 52cm (9-inch to 20-inch). The systolic blood pressure and diastolic blood pressure are measured by non-invasive blood pressure ("NIBP") measuring method and also by utilizing the Auto auscultation method and Oscillometric method. The KOROT P3 Accurate may provide useful clinical information about the current health status of not only the users who are diagnosed with hypertension but also those who are not diagnosed with hypertension.
Blood pressure is the measurement of pressure of blood circulating the walls of blood vessels. Blood pressure can be measured by direct or indirect measurement. This equipment supports indirect measurement using cuff. This equipment tracks and analyzes the blood flow oscillations under the pressure using the cuff from the highest to the lowest pressure as shown by the figure below when the minute pressure speed is determined by the heartbeat. This equipment adopts Oscillometric method and automated auscultation method using a cuff for blood pressure measurement. In case of Oscilometric method, the device determines the systolic, diastolic and pulse rate on the basis of the blood flow oscillations measured through the cuff. On the other hands, in case of Auto auscultation method, it is a method that combines the accuracy of auscultation, which is regarded as the gold standard for blood pressure measurement. To measure the blood pressure, wrap the cuff around the upper arm and inflate it to a pressure above the systolic pressure. Then slowly release the air to detect the Korotkoff sound signal and the pressure sensor signal, which you can catch with the sensor attached to the cuff, to measure the systolic and diastolic blood pressure. The Automated Auscultation applied to KOROT P3 Accurate combines the accuracy of the auscultation method that the medical staffs hear directly with the convenience of easy measurement. The signals are electronically processed to compensate for the possible errors in the auscultation method caused by movement, external noise, etc., enabling a more accurate blood pressure measurement.

*Cuffs: KR-CGM01, KR-CGL01, KR-CGML1, KR-CGXL1, KR-CDM01, KR-CDL01, KR-CDML1

*Bluetooth is only used to transmit data from the device to KOROT program and not used for active patient monitoring

Intended Use/Indications for Use

This blood pressure monitor is designed to measure blood pressure (diastolic and systolic) and pulse rate in adult patients with arm circumference range between 22 cm - 52 cm.

Indications for Use Comparison

The indications for use is identical except the range of arm circumference. So, we performed additional validation including the range of 42 to 52cm.

Technological Comparison

All the modifications were verified with rationales and we concluded that the subject device is substantially equivalent to the predicate device in terms of intended use, safety and effectiveness. The device has the same technological characteristics with the predicate device except the modifications below;

- Expansion of the arm circumference range (22cm~52cm)
- Addition of Bluetooth
- GUI change
- Addition of functions
- Component change
- Improved pulse accuracy
- Improved data storage
- Transport/Storage condition change

Non-Clinical and/or Clinical Tests Summary & Conclusions

For non-clinical test, all necessary bench testing were conducted on the subject device to support the determination of substantial equivalence to the predicate device. Not only the same standards and methods which are used to support the predicate device, but also the additional standards and methods were used for the subject device to support the equivalence and modifications.
For clinical test, the additional clinical data were collected for the extra range of the upper arm circumference and the totality of the clinical data from 22 to 52 cm supported the device's claim of being applicable to patients with upper arm circumference

from 22 to 52 cm, in accordance with the ISO 81060-2.